

Phase IIB Competing Renewal Awards

NOTE: The Solicitations and topics listed on this site are copies from the various SBIR agency solicitations and are not necessarily the latest and most up-to-date. For this reason, you should use the agency link listed below which will take you directly to the appropriate agency server where you can read the official version of this solicitation and download the appropriate forms and rules.

The official link for this solicitation is: <http://grants.nih.gov/grants/guide/pa-files/PA-12-088.html>

Agency:
Department of Health and Human Services

Release Date:
January 31, 2012
Branch:
n/a

Open Date:
January 31, 2012
Program / Phase / Year:
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Application Due Date:
January 08, 2013

Solicitation:
[PA-12-088](#)

Close Date:
January 08, 2013
Topic Number:
2.1

Description:

NIA accepts Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products, primarily for pharmaceutical compounds and medical devices, requiring regulatory approval by the Food & Drug Administration (FDA). NIA will accept applications for up to two (2) years and up to \$750,000 per year in total costs. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to advance research to a stage where interest in and investment by third parties would be more likely.

Prospective Phase IIB Competing Renewal applicants are strongly encouraged to submit a letter of intent to Dr. Kerns that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Anticipated Budget
- Participating institutions

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- Funding Opportunity Announcement Number (e.g., PA-12-XXX, if relevant)

Although a letter of intent is not binding and does not enter into the review of a subsequent application, it allows NIA staff to estimate the potential review workload, plan the review, and consider budget implications. It is anticipated that only a small number of NIA SBIR/STTR Phase II awards would be eligible for a Phase IIB Competing Renewal award.

The following examples would make appropriate topics for Phase IIB Competing Renewal projects. These are meant only as indications of potential Phase IIB Competing Renewal projects and are not exclusive of other appropriate activities. Research and development efforts can be focused, for example, on medications to treat, delay the progression of or prevent age-related cognitive decline, mild cognitive impairment (MCI), Alzheimer's disease, and other dementias of aging.

1. Studies for preclinical discovery and development of drugs, natural products, or other types of compounds, including pharmacology and toxicology studies, beyond those conducted under the initial SBIR Phase I and Phase II grants. The studies conducted under the previous grants should be sufficient to provide a sound rationale for continued development of the compound, drug or natural product.
2. Completion of studies as required by the FDA for an IND application.
3. Human clinical trials/studies to determine a drug's, natural product's, or other type of compound's safety profile, metabolism, and/or efficacy.

For questions relating to Phase IIB Competing Renewal applications, please contact:

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